Supreme Court, U. S.
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IN THE

Supreme Court of the United States

OCTOBER TERM, 1978

No. 78-1850

JAMES ROBERT PRIVITERA, JR.,

Petitioner,

v.

THE STATE OF CALIFORNIA,

Respondent.

PETITION FOR A WRIT OF CERTIORARI TO THE SUPREME COURT OF CALIFORNIA

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INDEX

	Pages
OPINIONS BELOW	1
JURISDICTION	2
QUESTIONS PRESENTED	2 - 3
CONSTITUTIONAL PROVISIONS AND STATUTES INVOLVED	3 - 8
STATEMENT	8 - 10
REASONS FOR GRANTING THE PETITION	10 - 22
CONCLUSION	23
APPENDIX A (OPINION OF SUPREME COURT)	A1 - A110
APPENDIX B (ORDER ON PETITION FOR REHEARING)	B1
APPENDIX C (OPINION OF COURT OF APPEALS)	C1 - C120

CITATIONS

CASES:

Paul v. Davis (1976) 424 U.S. 693	10
Planned Parenthood of Central Missouri v. Danforth (1976) 428 U.S. 52	15,16,17
Roe v. Wade (1973) 410 U.S. 113	14,15,16
United States v. Rutherford No. 78-605, Oct. Term 1978	20,21,22

	Pages
Whalen v. Roe (1977) 429 U.S. 589	10,11,12
CONSTITUTIONAL PROVISIONS:	
UNITED STATES CONSTITUTION	
Amendment XIV	3
STATUTES	
Food, Drug and Cosmetic Act, Section 505 21 U.S.C. 355	5-8
California Health and Safety Code Section 1707.1	3-5

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The petitioner, James Robert Privitera, Jr., respectfully prays that a writ of certiorari issue to review the judgment and opinion of the Supreme Court of the State of California rendered in these proceedings on March 15, 1979.

OPINIONS BELOW

The opinion of the Supreme Court (App. A, infra, pp. A1 - A110) is not yet reported. The order denying

petition for rehearing in the Supreme Court appears at Appendix B, infra, p. B-1. The opinion of the Court of Appeals (App. C, infra, pp. C1 - C120) is reported at 74 Cal.App. 3d 936, 141 Cal.Rptr. 764.

JURISDICTION

The judgment of the Supreme Court of California was entered on March 15, 1979. This petition for certiorari was filed less than 90 days from the date aforesaid. The jurisdiction of this Court is invoked under 28 U.S.C. § 1257(3).

QUESTIONS PRESENTED

1. Whether the imposition of criminal sanction on a licensed physician for prescribing laetrile as a cancer treatment for an informed consenting cancer patient, without first seeking governmental approval of its safety and effectiveness, serves a compelling state interest.

2. Whether denial of laetrile from a licensed physician to cancer patients who have unsuccessfully sought relief from conventional therapy and who are

fully informed as to the consensus of scientific opinion concerning laetrile is reasonably related to the preservation and protection of the public health.

CONSTITUTIONAL PROVISION AND STATUTES INVOLVED

Constitution of the United States, Amendment XIV, § 1:

"...nor shall any state deprive any person of life, liberty, or property without due process of law..."

California Health and Safety Code Section 1707.1 provides:

> The sale, offering for sale, holding for sale, delivering, giving away, prescribing or administering of any drug, medicine, compound or device to be used in the diagnosis, treatment, alleviation or cure of cancer is unlawful and prohibited unless (1) an application with respect thereto has been approved under Section 505 of the Federal Food, Drug and Cosmetic Act [21 U.S.C. § 355], or (2) there has been approved an appli-

cation filed with the board setting forth:

(a) Full reports of investigations which have been made to show whether or not such drug, medicine, compound or device is safe for such use, and whether such drug, medicine, compound or device is effective in such use;

(b) A full list of the articles used as components of such drug, medicine, compound or devices;

(c) A full statement of the composition of such drug, medicine, compound or device;

(d) A full description of the methods used in, and the facilities and controls used for, the manufacture, processing and packing of such drug, medicine or compound or in the case of a device, a full statement of its composition, properties and construction and the principle or principles of its operation;

(e) such samples of such drug, medicine, compound or device and of the articles used as components of the drug, medicine, compound or device as the board may require; and

(f) Specimens of the labeling and advertising proposed to be used for such drug, medicine, compound or device.

Section 505 of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 355, provides in part:

(a) No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) of this section is effective with respect to such drug.

(b) Any person may file with the Secretary an application with respect to any drug subject to the provisions of subsection (a) of this section. Such person shall submit to the Secretary as a part of the applica-

tion (1) full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use * * *

* * * * *

(d) If the Secretary finds * * * that (1) the investigations * * * required to be submitted to the Secretary * * * do not include adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof; (2) the results of such tests * * * do not show that such drug is safe for use under such conditions; * * * (4) * * * he has insufficient information to determine whether such drug is safe for use under such conditions; or (5) * * * there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling

thereof, or (6) based on a fair evaluation of all material facts, such labeling is false or misleading in any particular; he shall issue an order refusing to approve the application. * * * As used in this subsection and subsection (e) of this section, the term "substantial evidence" means evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it would fairly and responsibly be concluded by such experts that the drug will have effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof.

* * * * *

(i) The Secretary shall promulgate regulations for exempting from the operation of the foregoing subsections of this section drugs intended solely for investigational use by

experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs. Such regulations may, within the discretion of the Secretary, among other conditions relating to the protection of the public health, provide for conditioning such exemption upon—

(1) The submission to the Secretary, before any clinical testing of a new drug is undertaken, of reports, by the manufacturer or the sponsor of the investigation of such drug, of preclinical tests (including tests on animals) of such drug adequate to justify the proposed clinical testing. * * *.

STATEMENT

The petitioner, James Robert Privitera, Jr., a licensed medical doctor, was convicted by jury on December 16, 1975, of conspiring with his co-defendants to prescribe and sell laetrile to cancer patients for the alleviation or cure of cancer in violation of California Health and Safety Code Section 1707.1.

Dr. Privitera prescribed laetrile for cancer patients and referred patients to his co-defendants to buy laetrile.

All the cancer patients, whether state or defense witnesses, were knowledgeable persons fully aware of the nature of state sanctioned cancer therapies before seeking treatment from Dr. Privitera.

On November 10, 1977, the State Court of Appeal, Fourth District, reversed the judgment of the trial court and held that: (1) Section 1707.1 violated state and federal constitutional rights of privacy of the patient and the physician; (2) Section 1707.1 is not reasonably related to the expressed legislative purpose of preventing fraud; and (3) a search warrant was improperly issued and therefore invalid.

On March 15, 1979, a majority of the state Supreme Court reversed the Court of Appeal and held that: (1) Section 1707.1 did not violate state and federal constitutional rights of privacy, (2) Section 1707.1 bears a reasonable relationship in the achievement of the legitimate state interest in the health and safety of its citizens, and

(3) the search warrant issue was not preserved by appropriate objection below.

On April 12, 1979, the Supreme Court denied Dr. Privitera's petition for rehearing.

REASONS FOR GRANTING THE WRIT

1. The Court below has decided a federal question of substance in a way probably not in accord with applicable decisions of this Court.

In holding that a state can condition an informed individual's right to pursue a particular course of medical treatment from a licensed physican on state approval of that treatment, the California Supreme Court found no fundamental right of privacy or personal liberty involved and said: "But the kinds of 'important decisions' recognized by the high court to date as falling within the right of privacy involve 'matters relating to marriage, procreation, contraception, family relationships, and child rearing and education' (Whalen v. Roe, 429 U.S. at p. 600, FN.26, quoting Paul v. Davis (1976) 424 U.S. 693, 713),

but do not include medical treatment."

In Petitioner's view, the court below ignored the analysis of the Court in Whalen. This Court found in Whalen an implication of a privacy "interest in independence in making certain kinds of important decisions" in matters pertaining to the care of one's health. But the Court upheld the New York statutory scheme in Whalen because "neither the immediate nor the threatened impact" of the scheme on the "independence of patients for whom Schedule II drugs are medically indicated is sufficient to constitute an invasion of any right or liberty protected by the Fourteenth Amendment."

Before reaching this conclusion, the Court stated the following reasons:

> Nor can it be said that any individual has been deprived of the right to decide independently, with the advice of his physician, to acquire and to use needed medication. Although the State no doubt could prohibit entirely the use of particular Schedule

II drugs, it has not done so. This case is therefore unlike those in which the Court held that a total prohibition of certain conduct was an impermissible depreva-tion of liberty. Nor does the State require access to these drugs to be conditioned on the consent of any state official or other third party. Within dosage limits which appellees do not challenge, the decision to prescribe, or to use, is left entirely to the physician and the patient.

In this case, the substance in question, laetrile, is not narcotic, habit forming, hallucinatory, or toxic such as the dangerous "Schedule II" drugs in Whalen. The state does require that access to laetrile be conditioned on the consent of state officials. The informed consenting cancer patient has been deprived of the right to decide independently, with the advice of his physician, to acquire and to use

needed medication. The decision to prescribe, or to use, is left entirely to the prior approval of the state. This case is like those in which the Court held that a total prohibition of certain conduct was an impermissible deprivation of liberty.

The immediate impact of the decision is to deny treatment with an otherwise harmless substance to informed consenting individuals who have a disease with potentially fatal consequences, and the criminalization of the licensed physician who felt it appropriate to prescribe laetrile to those cancer patients. The state sanctioned treatments of surgery, chemotherapy, and radiation therapy involve the presence of physical pain, the creation of anxiety and apprehension of medical or other damage, permanent disfigurement and complications, risk of irreversible injury to health, and danger to life itself. The immediate impact of this decision necessitates acceptance of these risks or turns the matter of treatment back to the patient without any assistance from a licensed physician.

The court below also stated: "The lesson of Roe v. Wade [(1973) 410 U.S. 113] for our case is that a requirement that a drug be certified effective for its intended use is a reasonable means to insure maximum safety for the patient."

The court's reasoning would mean that no legal difference would exist between the terms "safe" and "effective." Roe dealt specifically with choice of medical treatment. This Court made it clear that during the first trimester of pregnancy, when abortion is less hazardous in terms of the woman's life than carrying the child to term would be, the state may require only that the abortion be performed by a licensed physician. No further regulations are compelling justified. After the first trimester, the compelling state interest in the mother's health permits it to adopt reasonable regulations, not a complete ban, in order to promote safe abortions. But requiring abortions to be performed in hospitals or only after approval of another doctor or committee in addition to the woman's physician,

is impermissible.

The broad sweep of the opinion below would mandate state sanctioned treatments or nothing at all for cancer patients too frail for state sanctioned treatments and for cancer patients diagnosed as terminal for whom state sanctioned treatments are useless. For patients too frail for state sanctioned treatments, nutritional treatment that includes laetrile is less hazardous in terms of the patient's life than state sanctioned treatments would be. For patients diagnosed as terminal by competent medical advisors, the terms "safe" and "effective" have no reasonable application. The lesson to be learned from Roe is that at least until the medical treatment sought to be prohibited is more dangerous than the state sanctioned alternatives, the Constitutional right of privacy protects the one seeking treatment and the physician who offers that treatment.

The court below also stated: "Planned Parenthood [(1976) 48 U.S. 52] thus stands for the proposition that although the decision to have an abor-

tion may be within the constitutional zone of privacy deserving the protection provided by the compelling interest standard, the selection of a particular procedure is a medical matter to which privacy status does not attach and which may be regulated by the government, providing a rational basis for such regulation exists."

This ignores that in Planned Parenthood the Court invalidated a state prohibition on the use of saline ammiocentesis as a method of abortion after the first twelve weeks of pregnancy. As in Roe, the "compelling point" was not reached until after the first trimester when the treatment sought to be prohibited approached the point of being more dangerous than the state sanctioned alternatives. Even after reaching the "compelling point, "the Court recognized that saline ammiocentesis was not harmful to the patient and held that the flat prohibition of the substance was a restriction which does not reasonably relate to the preservation and protection of maternal health.

Planned Parenthood contains the lesson from Roe that until the medical treatment sought to be prohibited is more dangerous than the state sanctioned alternatives, the Constitutional right of privacy protects the one seeking treatment and the physician who offers that treatment. The lesson to be learned from Planned Parenthood is that the flat prohibition of a medical treatment administered by a licensed physician that is not harmful to the patient does not reasonably relate to the preservation and protection of the public health. Therefore, the flat prohibition of a medical treatment that is safer for the particular patient than the state sanctioned alternatives certainly cannot be reasonably related to the preservation and protection of the public health.

No right or individual liberty is more fundamental, historic or traditional than the individual medical decision about how to survive. In balancing changing competing social values that revolve around this fundamental right,

the Court has provided clear principles and boundaries to govern unjustified intrusions into the individual decision making process. Until the medical treatment sought to be prohibited is more dangerous than the state sanctioned alternatives, the Constitutional right of privacy and personal liberty protects the one seeking treatment and the physician who offers that treatment. The court's decision below would change those principles and boundaries and allow the state to make this most fundamental decision without consultation with the patient.

2. The protection of the rights of other citizens is involved.

The case is important to Petitioner in that Petitioner will have to serve a term in jail if the writ is not granted. The case is important to individual cancer victims afflicted with a horrible disease who want to make their own decisions concerning the treatment they will pursue in an attempt to preserve their health or save their lives. The case also involves a frightening governmental intrusion into

an area which has been historically recognized as the domain of the individual. It involves the imposition on individuals of highly personal and subjective decisions affecting the most important and intimate aspects of their lives by an impersonal bureaucracy to which they have no access. Decisions are made for individual cancer victims by an inaccessible bureaucracy which controls the context of facts and values in which policies are shaped. Long after the laetrile controversy has been decisively settled within the medical and scientific communities, the legal principles established in this case will have a profound effect on the relationship, and the respective rights, of government and its citizens.

The decision below, as it stands, moves this nation one step closer to the establishment of a society in which the government, under the guise of protecting the ignorant, the gullible and the foolhardy, assumes the right to control knowledge and make decisions concerning the most intimate and personal aspects of the lives

of all of the people. Social and political power is kept from citizens in the form of "knowledge." Decisions are made under standards of "rationality" decreed and applied by large bureaucratic entities to which the people have no meaningful access. The people have been deprived of the right to control their own lives, and have lost the individuality which is the essence of their humanity. Government is given the power to control men's minds. The individual becomes a mere creature of the state and a vehicle for other people's views.

In a Constitutional government that recognizes the right of individuals to enjoy life and liberty and to pursue happiness, this kind of governmental intrusion cannot be tolerated.

3. The decision below raises problems similar to those now pending before the Court regarding the validity and application of Food, Drug and Cosmetic Act Section 505, 21 U.S.C. 355.

United States v. Rutherford, No. 78-605, Oct. Term 1978, which is presently

pending decision before the Court, raises substantially similar problems regarding the Constitutional validity and reasonable application of Section 505. As presently interpreted and applied by the Food and Drug Administration, Section 505 completely bans an informed cancer victim from receiving laetrile, an otherwise harmless but controversial treatment, unless the prior consent of government officials is obtained.

California Health and Safety Code Section 1707.1 adopts substantially similar procedures as contained in Section 505 for obtaining prior consent of state officials. Section 1707.1 specifically incorporates Section 505 as a method of obtaining prior consent of state officials. As interpreted and applied by the court below, Section 1707.1 completely bans an informed consenting cancer patient from receiving laetrile from a licensed physician unless the prior consent of state officials is obtained.

Rutherford does not raise Constitutional problems in terms of facts wholly

identical to those here involved. Petitioner, a licensed medical doctor, stands convicted of a crime for prescribing laetrile which is not narcotic, habit forming, hallucinatory or toxic to knowledgeable persons fully aware of the nature of state sanctioned cancer therapies before seeking treatment from Petitioner.

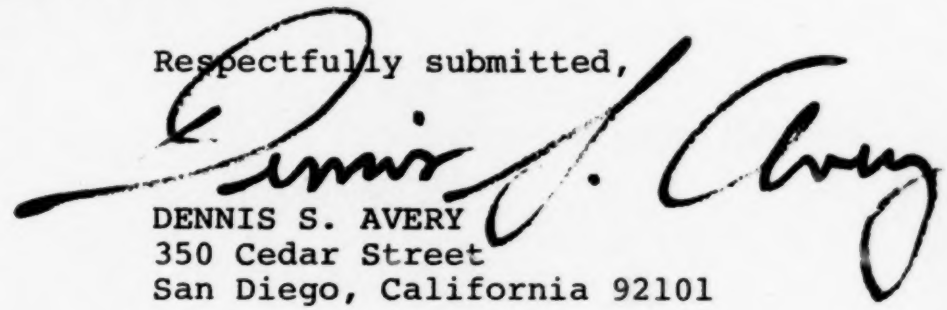
If the Court finds in Rutherford that a total prohibition of the cancer victims informed decision to use and obtain laetrile is an impermissible deprivation of liberty or not reasonably related to the preservation and protection of the public health, this case may be controlled by the Rutherford result.

It would therefore seem appropriate to withhold action on the instant petition until the Rutherford case has been resolved by this Court and to assess the appropriateness of reviewing the Constitutional ruling below in light of the decision in that case.

CONCLUSION

For these reasons, a writ of certiorari should issue to review the judgment and opinion of the California Supreme Court.

Respectfully submitted,



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